UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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| DEPOMED, INC,<br><br>Plaintiff(s),<br><br>v.<br><br>ACTAVIS ELIZABETH LLC, et al.<br><br>Defendant(s). | Civil Action No. 12-1358 (JAP) |
| DEPOMED, INC,<br><br>Plaintiff(s),<br><br>v.<br><br>ZYDUS PHARMACEUTICALS (USA), INC. et al.,<br><br>Defendant(s). | Civil Action No. 12-2813 (JAP)<br><br>(Consolidated for pretrial purposes)<br><br>**OPINION** |

PISANO, District Judge.

These are patent infringements actions brought by Plaintiff Depomed, Inc. ("Plaintiff" or "Depomed") against defendants, Actavis Elizabeth LLC, Acatvis Inc., Incepta Pharmaceuticals Co. Ltd., Abon Pharmaceuticals, LLC, Zydus Pharmaceuticals (USA), Inc., and Cadila Healthcare Ltd (together "Defendants"). Presently before the Court are the parties' requests for claim construction. The Court held a *Markman* hearing and has considered the written submissions of the parties, and this Opinion sets forth the Court's constructions of the disputed claim terms.

## I. BACKGROUND

Defendants in these actions have sought approval from the United States Food and Drug Administration ("FDA") to sell generic gabapentin once-daily tablets, a drug product that sells under the trade name Gralise. Gralise is used to treat postherpetic neuralgia, *i.e.*, pain from damaged nerves that follows the healing of shingles.[1] Plaintiff Depomed is the NDA holder for Gralise. The Orange Book has listed eight patents for Gralise, and Depomed has asserted seven of these patents in this action: U.S. Patent No. 6,340,475 (the " '475 patent"), U.S. Patent No. 6,488,962 (the " '962 patent"), U.S. Patent No. 6,635,280 (the " '280 patent"), U.S. Patent No. 7,438,927 (the " '927 patent"), U.S. Patent No. 7,731,989 (the " '989 patent"), U.S. Patent No. 8,192,756 (the " '756 patent"), and U.S. Patent No. 8,252,332 (the " '332 patent").

The '475 patent and '280 patent are directed towards "extending the duration of drug release within the stomach during the fed mode."[2] *See generally*, '475 patent and '280 patent. As explained in these patents, conventional tablets or capsules can release a drug too quickly when they come into contact with body fluids, which results in an unwanted transient overdose followed by a period of underdosing. Also, some drugs must be absorbed higher up in the gastrointestinal tract in order to be effective. The '475 and '280 patents address these and other related issues. These patents teach a dosage form comprising a "drug dispersed in a polymeric matrix" that "swells upon ingestion." '475 patent, col. 5, lines 57–63.[3] "[T]he swelling of the polymeric matrix … achieves two objectives--(i) the tablet swells to a size

[1] Shingles is a painful rash caused by an infection with the herpes zoster virus.
[2] "Fed mode" is a term used to describe the state of the stomach for a period after the ingestion of food.
[3] The '475 patent and '280 patent are based on the same patent application, Ser. No. 08/870,509, and, therefore, share the same disclosure. Where portions of the '475 patent are cited, those portions also appear in the ′280 patent, unless otherwise noted.

large enough to cause it to be retained in the stomach during the fed mode, and (ii) it retards the rate of diffusion of the highly soluble drug long enough to provide multi-hour, controlled delivery of the drug into the stomach." *Id.* col. 6, lines18–24.

The '962 patent covers "tablet shapes to enhance gastric retention of swellable controlled-release oral dosage forms." *See generally* '962 patent. The '962 patent teaches that dosage forms of particular shapes and sizes are both easy to swallow and resist escape through the pylorus into the intestines. *See id.* col. 3, lines 22–42. "The shape that achieves this result is a non-circular, non-spherical shape which, when projected onto a planar surface, has two orthogonal axes of different lengths[.]" *Id.* col. 3, lines 27–30. An example of a shape with these characteristics is an oval. *Id.* col. 4, lines 15–16. In addition, the dosage form must be of a size such that when the dosage form swells, the shorter axis of the dosage form expands to a size large enough so that it resists passage through the pylorus. *Id.* col. 4, lines 22–31.

The '927, '989, '756 and '332 patents describe gastric retained dosage forms containing gabapentin. According to these patents, by extending the time period for which the gabapentin dosage form is retained in the stomach, the prolonged duration of the transit time provides for improved gabapentin absorption because gabapentin is known to be absorbed in the upper, but not the lower, gastrointestinal tract. *See, e.g.*, '927 patent, col. 1. Lines 25-36, col 2, lines 14-25. The patents are also directed to methods of treating conditions specifically treated by gabapentin – epilepsy and neuropathic pain – using the gastric retained dosage forms. *Id.* at col 1, lines 54-64.

## II. LEGAL STANDARDS

In order to prevail in a patent infringement suit, a plaintiff must establish that the patent claim "covers the alleged infringer's product or process." *Markman v. Westview Instrs., Inc.*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotations omitted) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("we look to the words of the claims themselves ... to define the scope of the patented invention"). Consequently, the first step in an infringement analysis involves determining the meaning and the scope of the claims of the patent. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed. Cir. 1995). Claim construction is a matter of law, *Markman v. Westview Instrs., Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) *aff'd* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), therefore, it is "[t]he duty of the trial judge ... to determine the meaning of the claims at issue," *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995).

Generally, the words of a claim are given their "ordinary and customary meaning," which is defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1312–13 (citations omitted). In this regard, the Federal Circuit has noted that

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention—the inventor's lexicography—must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the

> court starts the decisionmaking process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history.

*Id.* (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)).

In order to determine the meaning of a claim as understood by a person skilled in the art, a court may look to various sources from which the proper meaning may be discerned. These sources include intrinsic evidence, which consists of "the words of the claims themselves, the remainder of the specification, [and] the prosecution history," *id.* at 1314, and extrinsic evidence "concerning relevant scientific principles, the meaning of technical terms, and the state of the art," *id.*

When considering the intrinsic evidence, the court's focus must begin and remain on the language of the claims, "for it is that language that the patentee chose to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.' " *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed.Cir.2001) (quoting 35 U.S.C. § 112, ¶ 2). The specification is often the best guide to the meaning of a disputed term. *Honeywell Int'l v. ITT Indus.*, 452 F.3d 1312, 1318 (Fed.Cir.2006). It is improper, however, to import limitations from the specification into the claims. *Seachange Int'l v. C–COR Inc.*, 413 F.3d 1361, 1377 (Fed. Cir. 2005). The court may also consider as intrinsic evidence a patent's prosecution history, which is evidence of "how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317.

While a court is permitted to consider extrinsic evidence, such evidence is generally of less significance and less value in the claim construction process. *Id.* at 1317. Extrinsic evidence is evidence that is outside the patent and prosecution history, and may include expert testimony, dictionaries, and treatises. *Id.* The Federal Circuit has noted that caution must be exercised in the use of extrinsic evidence, as this type of evidence may suffer from inherent flaws affecting its reliability in the claim construction analysis. *Id.* at 1319 ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms."). While "extrinsic evidence may be useful to the court, ... it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." Extrinsic evidence may never be used to contradict intrinsic evidence. *Id.* at 1322–23.

## III. CONSTRUCTION OF THE DISPUTED CLAIM TERMS

There are many claims asserted by Plaintiff in these actions and, correspondingly, a number of claim terms are disputed by the parties. Disputed claim terms that are related are grouped as set forth below:

### A. "Gastric Retained" Group of Terms

These disputed claim terms below are found in claims 1, 8-15, 61 and 62 of the '475 patent; claims 1, 8-15, 45 and 46 of the '280 patent; claims 17-19, 23, 25, 26, 30, 32-35, 39-43, 45, 50, 52, 53, 55, 56, 59 and 61-63 of the '927 patent; claims 1-7, 10-15, 19 and 20 of the '989 patent; and claims 1-12, 15 and 16 of the '756 patent.

1. *"thereby attaining a size large enough to promote retention in the stomach during said fed mode"*

This term appears in the '475 patent, and has been construed by this Court previously in the action *Depomed Inc. v. Sun Pharma Global FZE,* Civil Action No. 3:11-cv-03553 ("*Sun Pharma*"). In that action, the Court construed this term to mean "such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours." That is the same construction applied by another district court in *Depomed, Inc. v. Lupin Pharm., Inc. et al.*, No. 09-05587-PJH (N.D. Cal. 2011) (Hamilton, J.) ("*Lupin*") (construing the disputed term to mean "such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours"). *See* Sadasivan Decl., Ex. 9. The disputed claim language also has been similarly construed in *Depomed, Inc. v. Ivax Corp.*, No. 06-00100-CRB (N.D. Cal. 2006) (Breyer, J.) to mean "such that when introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours." *See* Sadasivan Decl., Ex. 10.

Plaintiffs here argue that the Court should adopt its earlier construction, a construction that is consistent with the constructions adopted by the two other courts. Defendants, on the other hand, urge a different construction, asserting that the disputed term should be construed as follows: "such that when the dosage form is introduced into the stomach in the fed mode, it attains a size such that the dosage form remains in the stomach for the duration of drug delivery."

The key difference between the parties' constructions centers on the duration of the retention of the dosage form in the stomach. The previous constructions as well as Plaintiff's proposed construction are temporal; the dosage form remains in the stomach "for several

hours." Defendants' proposed construction is more functional; the dosage form must remain in the stomach until the entirety of the drug is delivered.

Defendants have not presented the Court with a reason to depart from the earlier constructions. The specification of the '475 patent is clear that that delivery of drug takes place over several hours. The patent, for example, states that "[t]he swollen polymeric matrix … remains in the gastric cavity for **several hours** when administered while the patient is in a fed mode, and remains intact long enough for substantially all of the drug to be released before substantial dissolution of the matrix occurs." '475 patent at Abstract (emphasis added). The patent further notes that the dosage form swells so as to be retained in the stomach and "retards the rate of diffusion of the highly soluble drug long enough to provide **multi-hour**, controlled delivery of the drug into the stomach." '475 patent, col. 6, ll. 19-24 (emphasis added). Example 9 of the '475 patent discloses that in human subjects in a fed state, retention in the stomach was measured as ranging from 4 to 10 hours. '475 patent, Example 9, col. 17, ll. 19-23.

In sum, the term at issue speaks of the drug residing in the stomach, and the intrinsic evidence defines that residence in terms of time rather than drug delivery. Defendants' proposed construction would import limitations into the claim that are not properly there. As such, consistent with Plaintiff's proposed construction, the Court adopts its earlier construction and construes this disputed term to mean "such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours."

2. *"is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode"*

This term appears in the '280 patent. As with the above term, Plaintiff asks the Court to adopt its construction from *Depomed Inc. v. Sun Pharma Global FZE,* Civil Action No. 3:11-cv-03553, specifically: "such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours" Defendants, on the other hand, seek the following construction: "is of a size exceeding the pyloric diameter in the fed mode such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for the duration of drug delivery." For the reasons discussed above, the Court finds no reason to depart from its earlier construction, and adopts its construction from the *Sun Pharma* case, *supra*.

3. *"to increase its size to promote gastric retention of the dosage form in the stomach of a mammal"*

This term appears in the '927 patent. Similar to the terms in this group discussed above, Plaintiff argues that the Court should adopt an earlier construction for a similar term from the *Sun Pharma* case. Specifically, Plaintiff points to the Court's prior construction for the term "attaining a size large enough to promote retention in the stomach" in the *Sun Pharma* case, and contends the Court should construe the instant term to mean "such that when the dosage form is introduced into the stomach, the dosage form remains in the stomach for several hours". Defendants, on the other hand, offer the following proposed construction: "to increase in size to allow for extended release of drug substance in the stomach of a mammal for the duration of drug delivery independent of the intake of food." As compared with the gastric-retained terms discussed above, Defendants' proposed construction here also

includes the requirement of being "independent of fed mode." Defendants offer this differing proposed construction because the claim language here states "in which a fed mode has been induced" as opposed to "during the fed mode" or "in . . . a fed mode" as is found in the language of the claims referenced above. Defendants point to the differing syntax and argue that it shows that the instant claim term requires a construction that gastric retention is independent of induction of the fed mode. However the Court finds the express claim language "in which a fed mode has been induced" to be amply clear that fed mode is a requirement. Defendants have argued nothing that alters that, and their proposed construction contradicts this plain claim language. Consequently, for the reasons discussed above, the Court adopts its construction from the *Sun Pharma* case, *supra*, and construes this term to mean "such that when the dosage form is introduced into the stomach, the dosage form remains in the stomach for several hours".

4a. *"increase its size to promote gastric retention of the dosage form in a stomach in a fed mode"* ('989 patent)

4b. *"to increase its size to promote gastric retention of the dosage form in the stomach in a fed mode"* ('756 patent)

For these two disputed terms, Plaintiff again argues that the Court should adopt a construction from the *Sun Pharma* case, specifically: "such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours". Defendants propose the following construction: "to increase in size such that when introduced into the stomach in the fed mode, the dosage form remains in the stomach for the duration of drug delivery." For the reasons stated above with respect to the other

gastric-retained claim terms, the Court rejects Defendants' proposed construction and adopts its construction from the *Sun Pharma* case.

5. "*dispersed in a gastric retained dosage form*"

This term appears in the '927 patent. Plaintiff contends that this term is well understood in the art and does not require construction; therefore, its plain and ordinary meaning should apply. Defendants offer the following proposed construction: "contained in a dosage form that allows for extended release of drug substance in the stomach for the duration of drug delivery independent of the intake of food." Defendants' proposed construction, however, imports a number of unnecessary limitations into this disputed phrase. For example, it is unnecessary to include the limitation of "extended release" here as the measure of release is plainly provided for elsewhere in the claim. *See, e.g.* '927 patent, claim 17 ("is released by diffusion from the dosage form over a period of at least five hours"). Further, as discussed above, the language "for the duration of drug delivery" is not supported by the relevant evidence. Consequently, the Court rejects Defendants' proposed construction. The Court agrees with Plaintiff that the term's plain and ordinary meaning would be clear to one that is skilled in the art and, therefore, no construction is necessary. The phrase's plain and ordinary meaning shall apply.

B. "Administration" Group of Terms

This set of claim terms are the "administration" group of terms. These terms are found in claims 17-19, 23, 25, 26, 30, 32-35, 39-43, 45, 49, 50, 52, 53, 55, 56, 59 and 61-63 of the '927 patent; claims 1-7, 10-15, 19 and 20 of the '989 patent; claims 1-12, 15 and 16 of the '756 patent; and claim 19 of the '332 patent. There are a total of seven claim terms that fall under this category.

1a. *"administration"* ('927 patent, claims 17, 33; '989 patent, claim 1; and '756 patent, claims 1, 6, 15);

1b. *"wherein the hydrophilic polymer swells to approximately 115% of its original volume within one hour of administration"* ('927 patent, claims 49, 50);

1c. *"wherein the dosage form swells to approximately 115% of its volume prior to administration within one hour after administration"* ('989 patent, claim 2);

1d. *"wherein the dosage form swells to approximately 130% of its volume prior to administration at a time later than one hour after administration"* ('989 patent, claim 3)

1e. *"the ratio of the maximum plasma concentration to the plasma concentration at 15 hours after administration is no more than about 2"* ('332 patent, claim 19)

This subgroup of terms centers on the word "administration." Plaintiff argues that the term "administration" need not be construed because it is a well-known term having a meaning that is apparent to one that is skilled in the art. Defendant asserts that the term should be construed to mean "providing [of a drug substance] to the body of a patient or mammal." Defendants rely upon the "context" of the term within the claims in support of their construction. They also point to portions of the specification that describes the disputed terms as providing the drug to the body of a mammal:

> "administering . . . gabapentin . . . in a gastric retained dosage form to a mammal" and "administering a therapeutically effective amount of gabapentin to a patient in need thereof" ('927 patent, 1:60-67)
>
> "[f]or purposes of facilitating patient compliance, administration of any of the aforementioned additional agents at the same time is preferred" (*Id.* at 5:46-48)
>
> "gastric retained dosage form of gabapentin is an extended release oral drug dosage form for releasing gabapentin into the stomach, duodenum and small intestine of a patient." (*Id.* at 6:50-53)

Plaintiff takes issue with Defendants' proposed construction in that it would limit the disputed term to the *in vivo* context only. Plaintiff points to portions of the specification in support of their argument that the "administration" terms also apply in the *in vitro* context as well:

> "A typical dosage form would provide for a drug delivery profile such that gabapentin both on an in vivo and in vitro basis, is delivered for at least 5 hours . . . it is preferable that at least 40 wt % of gabapentin is retained in the dosage form after 1 hour, i.e., no more than 60 wt % of the drug is administered in the first hour." ('927 patent, col. 6, ll. 17-28)

When asked about the nature of the dispute with respect to these terms at oral argument, Plaintiff's counsel asserted that the adoption of Defendants' construction would prevent Plaintiff from introducing *in vitro* evidence at trial (*e.g.* to show that the gabapentin be released by diffusion over a period of at least five hours, etc.), a point that Defendants' counsel appeared to dispute. Indeed, it seemed that the parties had difficulty identifying the actual dispute underlying this term and the consequence of its construction on the litigation. As such, and having considered the parties' respective positions, the Court agrees with Plaintiff and does not find it necessary to construe the term "administration". Its meaning is clear to a person of skill in the art, therefore, its plain and ordinary meaning shall apply here.

2. *"wherein the dosage form provides <u>administration</u> of at least 80 wt% of the gabapentin to be delivered over a period of about 5-12 hours"* ('927 patent, claim 41)

This term appears in claim 41 of the '927 patent. Plaintiffs argue that construction of this term in not necessary and its plain and ordinary meaning should apply. Defendants propose the following construction: "wherein the dosage form provides to the body of the mammal at least 80 wt% of the gabapentin to be delivered over a period of about 5-12 hours". The construction offered by Defendants incorporates their proposed construction of the term

"administration," *supra*, into the existing claim language. The Court, however, concluded above that construction of the term administration was not required, and similarly rejects Defendants' proposed construction here. The meaning of the disputed term is clear to a person of skill in the art, therefore, its ordinary and customary meaning shall apply here.

3. *"wherein the administering achieves a reduced incidence of side effects to the central nervous system, relative to a non-gastric retained dosage form"*

This term appears in claims 52 and 53 of the'927 patent. Plaintiff contends that, like the other "administration" claim terms, no construction is required. Defendants argue that this term should be construed to mean "wherein the providing [of the drug substance] to the body of the mammal achieves a reduced incidence of side effects to the central nervous system, relative to a non-gastric retained dosage form". Again, Defendants have essentially incorporated their proposed construction for "administration" into this disputed claim term. For the reasons above, the Court shall not construe the claim, and its plain and ordinary meaning shall apply.

C. "Dimensionally Unrestricted" and "Dimensionally Unrestrained" Terms

1. *"said dosage form being one that when swollen in a dimensionally unrestricted manner as a result of imbibition of water"*

This term appears in claim 1 of '280 patent. Plaintiffs ask the Court to adopt the construction agreed to by the parties in *Sun Pharma* as follows: "the dosage form, which comprises a polymeric matrix, increases in size due to ingress of water." This was the construction given by Judge Hamilton to a phrase containing the term "dimensionally unrestricted" in by in *Lupin*. Defendants propose a construction as follows: "said dosage form being one that upon imbibition of water swells in a physically unlimited manner in all

dimensions." The main point of disagreement between the parties revolves around that portion of Defendants' proposed construction that refers to "physically unlimited" swelling, as Plaintiff argues that such a construction is an attempt by Defendants to build in a limitation on the rate or extent of swelling.

The Court has carefully considered each of parties' proposals and their arguments, but rejects both parties' constructions. Plaintiff's construction is not sufficient because merely stating that the dosage form "increases in size" fails to account for the "dimensionally unrestricted" language in the disputed term.[4] Defendants' construction is also flawed because it improperly limits swelling itself. This Court, as the *Lupin* court, rejects any limitation on the rate or extent of swelling, so long as there is swelling of the dimension of the dosage form. As stated in *Lupin*,

> the claim language requires that the dosage form swells or increases in size, and does not place any restriction on that swelling. However, Claim 1 of the '280 patent (the claim where the word "unrestricted" appears) refers to the dosage form being swollen in a "dimensionally unrestricted" manner. It is not the swelling itself that is unrestricted, but the swelling of the dimensions of the dosage form—that is, length, the width, or other dimension of the dosage form—based on the swelling characteristics of the selected polymer.

*Lupin*, 2011 WL 1877984 at *7. Therefore, the Court declines to construe the disputed term, but rather finds that for present purposes the term's plain and ordinary meaning shall apply.

[4] In the *Lupin* case, Judge Hamilton was construing two terms (one from the '475 patent and one from the '280 patent) that the parties in that case had agreed should have the same construction, but only one contained the "dimensionally unrestricted" language. The disputed term from the '475 patent being construed in *Lupin* included the language "swells upon imbibition of water" and the disputed term from the '280 patent included the language "swollen in a dimensionally unrestricted manner as a result of imbibition of water."

2. *"said matrix being one that swells in an unrestricted manner along both such axes upon imbibition of water"*

This term appears in claim 1 of the '962 patent. Plaintiff contends that this term is well understood by one skilled in the art and does not require construction. Defendants' proposed construction is as follows: "said matrix being one that swells in a physically unlimited manner along the two orthogonal axes upon imbibition of water."

Defendants' construction essentially tracks the language of the claim with the exception of the "physically unlimited" limitation. Contrary to the arguments of Defendants, the Court finds no basis in the intrinsic evidence to justify the addition of the limitation of "physically unlimited" in their proposed construction. The Court, rather, finds that the meaning of the disputed term is clear to a skilled artisan and, therefore, the plain and ordinary meaning of the term shall apply.

3a. *"swells in a dimensionally unrestrained manner by imbibing water" ('927 patent, claims 17, 33)*

3b. *"swells unrestrained dimensionally by imbibing water swells unrestrained dimensionally by imbibing water" ('989 patent, claim 1; '756 patent, claims 1, 6, 15)*

Plaintiff asserts that for both of these terms the Court should adopt its previous construction for the term "when swollen in a dimensionally unrestrained manner as a result of imbibition of water" in *Sun Pharma*, specifically "the polymeric matrix, increases in size due to ingress of water." Defendants argue that both of these terms should be construed to mean "swells in a physically unlimited manner in all dimensions upon imbibition of water." The Court here, again, finds the same flaws as discussed above in each parties' proposed

construction. Rejecting both proposed constructions, the Court declines to construe the disputed term, but rather finds that the term's plain and ordinary meaning shall apply.

D. "Single Matrix" Claim Terms

1. *"dispersed in a single polymer matrix"*

This term is found in claims 17 and 33 of the '927 patent, and in claim 1 of the'989 patent. Plaintiff offers the following proposed construction: "dispersed in a single medium comprising polymer." Defendants argue that the term does not require construction and its plain and ordinary meaning should apply. The parties dispute over this term centers upon whether, as Defendants contend, the '927, '989 and '756 patents claim formulations that contain only one polymer matrix that contains and controls the release of gabapentin from the dosage form. Said another way, Defendants contend that under the plain and ordinary meaning of this term there is "one and only one drug-containing matrix in the claimed dosage form." Def. Resp. Brf. at 26. Plaintiff argues to the contrary, pointing to the fact that the relevant patent claims use the word "comprising," which Plaintiff contends indicates that the dosage form contemplates one or more single (polymer) matrices.

The Court finds that the intrinsic evidence supports Defendants' position. As an initial matter, turning just to the plain language, the term "single" clearly means "only one." Moreover, the prosecution history shows that the patentee distinguished its "single polymer matrix" from the prior art's "plurality of particles." Specifically, during prosecution of the '927 patent, claims were rejected as obvious in light of the prior art Shell reference. That reference disclosed controlled-release dosage forms containing a drug dispersed within a plurality of particles in a swellable polymer. Murata Aff. Ex. 12d at 8-9. To overcome this rejection, the patentee amended the pending claims to explicitly add the "single polymer

matrix" limitation to the claims, *id.* Ex. 12b at 2, 4, 6, 8, and argued emphatically that this newly added limitation distinguished the claims from the Shell "plurality of particles." *See, e.g.*, Murata Aff. Ex. 12b at 20 ("Shell describes a "controlled-release oral dosage forms that comprise a tablet or capsule containing a *plurality* of particles … In contrast to Shell, Applicant's claimed dosage form is comprised of a single polymer matrix with drug dispersed therein."). Consequently, in accordance with the position of Defendants, the plain and ordinary meaning of the term "dispersed in a single polymer matrix," as described above, shall apply.

2. *"dispersed in a single matrix"*

This term is found in claims 1, 6, and 15 of the '756 patent. Plaintiff contends that this term should be construed to mean "dispersed in a single medium." Defendants argue that the term's plain and ordinary meaning should apply. The dispute over this claim term is exactly as with the previous term, and, therefore, the Court reaches the same result.

E. Remaining Terms

1. *"remains substantially intact"*

This term appears in claim 1 of the '475 patent and claim 1 of the '280 patent. Plaintiff contends that this term should be construed to mean "a polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles." Defendants proposes the Court construe the term to mean "a polymeric matrix in which the polymer portion substantially retains its size and shape after ingestion without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small

particles." The difference in the proposed constructions is that Defendants' construction adds the requirement "after ingestion," something not found in Plaintiff's construction.

Plaintiff's proposed construction is taken verbatim from the definition of "substantially intact" set forth in the '475 and '280 patents. *See* '475 patent, col. 9, ll. 35-40 ("The term 'substantially intact' is used herein to denote a polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles.") Also, the construction proposed was the construction adopted for this term by Judge Hamilton in by in *Lupin*. Defendants here simply have not established that it is necessary to add the limitation "after ingestion" in defining this term. Accordingly, the Court construes the term "remains substantially intact" to mean "a polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles."

2. *"gas generating agent"*

This term is found in claims 28 and 43 of the '927 patent. Plaintiff argues that no construction is required and that the term's plain and ordinary meaning should apply. Defendants contend that the term means "an agent capable of releasing carbon dioxide or nitrogen." Here, Defendants appear to have based their construction upon a particular embodiment taught by the '927 patent. The patent states that "[i]n one embodiment of the invention, the gastric retained dosage form of gabapentin . . . that comprises (a) at least one component that expands on contact with gastric juice and contains an agent capable of releasing carbon dioxide or nitrogen, . . ."'927 patent, Col. 6, ll. 29-34. The Federal Circuit, however, has warned against confining claims solely to disclosed embodiments. *See Linear*

*Technology Corp. v. International Trade Com'n*, 566 F.3d 1049, 1058 (Fed. Cir. 2009) ("We have repeatedly held that, even in situations when only one embodiment is disclosed, the claims generally should not be narrowed to cover only the disclosed embodiments or examples in the specification."); *Ventana Medical Systems, Inc. v. Biogenex Laboratories, Inc.*, 473 F.3d 1173, 1181 (Fed. Cir. 2006), ("[While] the fact that the disclosed embodiments are limited can assist in interpreting claim language ... [it] does not in and of itself mean that the method claims at issue are limited to the disclosed embodiments."); *Phillips*, 415 F.3d at 1323 (rejecting, "the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment"). As such, the Court rejects Defendants' proposed construction. The Court agrees with Plaintiff that this term does not require construction and the plain and ordinary meaning of the term "gas generating agent" shall apply.

3. *"bilayered or multilayered adhesive tablet"*

This term is found in claims 30 and 45 of the '927 patent. Plaintiff argues that no construction is required and that the term's plain and ordinary meaning should apply. Defendants contend that the term means "a tablet having only one gabapentin/polymer matrix layer and one or more additional layers."

The Court finds Defendants' construction of this disputed term to be consistent with the intrinsic evidence of the '927 patent. The claims containing the term "bilayered or multilayered adhesive tablet" depend from claims 17 and 33. Both claim 17 and claim 33 require a single polymer matrix that contains a swellable polymer that releases gabapentin through diffusion. While dependent claims 30 and 45 require at least two layers, a person of ordinary skill in the art would understand from the claim language "single polymer matrix,"

as the Court had construed that term above, that only one of the layers of the "bilayered or multilayered adhesive tablet" is the gabapentin/polymer matrix layer.

Further, where the specification describes a bilayer tablet, it states that "a bi-layer tablet releases gabapentin to the upper gastrointestinal tract from an active containing layer, while the other layer is a swelling or floating layer." '927 patent, col. 7, ll. 6-12. As Defendants argue, when read through the lens of the claims -- which require that the gabapentin is released by diffusion through a "single polymer matrix" -- the specification indicates that a bilayered or multilayered tablet contains a single gabapentin-polymer matrix layer and at least one additional layer that is not a gabapentin-polymer matrix layer.

Consequently, the Court disagrees with Plaintiff's argument that Defendants are merely limiting the claim to a particular embodiment found in the patent. *See* '927 patent, col. 7, ll. 6-9 ("In yet another embodiment, a bi-layer tablet releases gabapentin to the upper gastrointestinal tract from an active containing layer, while the other layer is a swelling or floating layer."). Defendants' proposed construction shall be adopted and the term "bilayered or multilayered adhesive tablet" is construed to mean "a tablet having only one gabapentin/polymer matrix layer and one or more additional layers."

4. *"without loss in bioavailability as measured by the area under the curve ($AUC_{infinity}$) as compared to the bioavailability which is achieved from an immediate release dosage form comprising the same dose of gabapentin"*

This term is found in claims 1 and 6 of the '756 patent. Plaintiff offers the following proposed construction: "bioavailability as measured by the area under the curve ($AUC_{infinity}$) is at least 80% of an equal dose of gabapentin in an immediate release dosage form." Defendants proposed construction is as follows: "without any loss in bioavailability as

measured by the area under the curve ($AUC_{infinity}$) as compared to the bioavailability which is achieved from an immediate release dosage form comprising the same dose of gabapentin." Under Plaintiff's construction, a loss of bioavailability of up to 20% would be permitted, while under Defendants' construction, absolutely no loss of bioavailability is permitted.

The Court finds Plaintiff's construction to be more consistent with the intrinsic evidence. In particular, the specification discloses that "the gastric retained dosage form is designed to provide for bioavailability of gabapentin at a level greater than or equal to 80% relative to an equal dose of an immediate release dosage form." '756 patent, col. 4, ll. 64-67. Consequently, "without loss in bioavailability as measured by the area under the curve ($AUC_{infinity}$) as compared to the bioavailability which is achieved from an immediate release dosage form comprising the same dose of gabapentin" shall be construed to mean "bioavailability as measured by the area under the curve ($AUC_{infinity}$) is at least 80% of an equal dose of gabapentin in an immediate release dosage form."

5. *"wherein the time to reach maximum plasma concentration is at least 5.6 hours ±34.9%"*

This term is found in claims 3 and 8 of the '756 patent and claims 2, 8, and 13 of the '332 patent. At oral argument, the parties agreed that this term means "wherein the time to reach maximum plasma concentration is 'between 3.6 [hours] or greater.' " Tr. 80:7-8

## IV. CONCLUSION

For the reasons set forth above, the disputed claim terms will be construed as indicated. An appropriate Order shall accompany this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: January 28, 2014